Activating *Actavis*: A More Complete Story

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IN *FTC V. ACTAVIS, INC.* THE SUPREME COURT asked whether a patent settlement agreement involving a so-called reverse payment from an incumbent producer (Brand) to an alleged infringer of a pharmaceutical patent (Generic) "can sometimes unreasonably diminish competition in violation of the antitrust laws."[1] The *Actavis* Court answered this question in the affirmative, rejecting the Eleventh Circuit's ruling that held that patent settlement agreements generally were lawful as long as their potential anticompetitive effects fell within the scope of the patent.

At the same time, the *Actavis* Court also rejected the FTC's view that settlements involving reverse payments should be deemed presumptively unlawful. In doing so, the Court in *Actavis* rejected a "quick look" approach for evaluating such agreements, which would presume illegality unless the Brand could prove that the settlement agreement had procompetitive effects. Instead, the *Actavis* Court held that in cases involving settlements with a "large" reverse payment, "the FTC must prove its case as in other rule-of-reason cases."[2]

In a recent article in this magazine, Edlin, Hemphill, Hovenkamp, and Shapiro (EHHS) propose a method of evaluating the competitive effects of reverse-payment settlement agreements that compares the magnitude of the reverse payment to the sum of the Brand's prospective litigation costs and the value of services provided by the Generic to the Brand.[3] According to EHHS's formulation, "[T]he plaintiff's case involves a narrowly focused inquiry."[4] EHHS propose that once the plaintiff has established that "the claimed infringer has agreed to abstain, in some respect, from competing using the patented technology" for some period, the plaintiff in its prima facie case must then value the consideration from the Brand to the Generic and establish only that the value of such consideration exceeds the Brand's litigation costs avoided through settlement.[5] If the plaintiff makes such a showing, EHHS propose that the defendant(s) must then prove that the excess reverse payment was reasonable consideration for services provided by the Generic. According to EHHS, any "otherwise unexplained" reverse payment after accounting for avoided litigation costs and the value of services provided by the Generic "may be understood to be payment for delaying entry."[6]

In effect, EHHS propose a rule that shifts the burden to the defendant once it is established that a reverse payment exceeds avoided litigation costs. EHHS's approach appears to ignore the language of the *Actavis* opinion that expressly rejects the "quick look" approach and finds that many factors need to be considered in a rule-of-reason analysis of reverse payments. The *Actavis* opinion notes:

> [T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, *and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.*[7]

The Court in *Actavis* thus recognized that an analysis of reverse payments in any particular settlement is complex. In contrast, EHHS's proposed approach fails to account for a variety of issues that may arise in the context of such settlements, including factors that indicate that reverse payments can result in settlements beneficial to consumers, with entry by the Generic occurring earlier than would have been expected in the absence of the settlement.

In the absence of the settlement, the statistically expected date of entry lies between the date of entry that would apply if the Brand were to lose the patent litigation and the date of entry that would apply if the Brand were to win the patent litigation, with the specific expected date within that range depending on the probabilities of the outcomes of the patent litigation (e.g., a date in the middle of the range if the probability of the Brand winning were 50 percent). A settlement with a reverse payment can benefit consumers if it: (1) causes the Brand to be willing to accept a settlement permitting entry on a date earlier than the expected entry date under litigation; and (2) results in a settlement that would not have occurred without a reverse payment. Such settlements would be procompetitive under the standard in *Actavis*.[8] EHHS's methodology and proposed jury instructions would preclude some procompetitive settlements because their economic model omits realistic factors (such as risk aversion and differing views of the settlors) that may render reverse payments necessary for attainment of a procompetitive settlement.

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Background on Patent Litigation Settlements

Settlements such as those at issue in *Actavis* occur when a Generic files an Abbreviated New Drug Application under Hatch-Waxman with a Paragraph IV Certification, triggering a patent infringement suit by the Brand against the Generic. For a settlement to occur, both the Brand and the Generic must view the settlement as preferable to their expected outcomes from litigation. Whether or not a negotiated settlement will occur, and the terms of the settlement, depend on the outcome of the bargaining process between the Brand and the Generic. Standard economic theories of bargaining express the outcome negotiated by two parties as a function of the potential payoffs to them through negotiation and their "threat points," which are the potential payoffs they can achieve if bargaining breaks down.[9] In this context, the threat points are the outcomes each party expects from litigation.

It is useful to first consider the likely terms of a settlement that involves no payment from the Brand to the Generic. Both the Brand and the Generic would incur costs to pursue a litigated outcome to their patent dispute. For present purposes, assume the Brand and the Generic are both risk-neutral, have the same time value of money, and share the same view about the likely outcome of litigation. Under these conditions, there exist potential settlements without reverse payments that should be preferred to litigation by both parties. Settlements are possible under these assumed circumstances because each party can agree on entry on or near the date that corresponds to the entry date that would be expected under litigation, while avoiding litigation costs.

Suppose instead that differences between the parties preclude such a settlement but that a reverse payment is a possible element of a settlement between the Brand and the Generic. Such payments expand the range of potential settlement outcomes, because the Brand's profits absent entry by the Generic likely exceed the sum of profits for the Brand and the Generic after Generic entry. Accordingly, a later entry date for the Generic in a settlement increases the total profits available to the Brand and the Generic. While a later entry date reduces the profits the Generic earns from entry, the Brand gains even more from the later entry. The difference can allow the Brand and Generic to bridge differences in negotiating positions arising from differences in viewpoints, information, and preferences, thereby enabling procompetitive settlements.

The EHHS Model

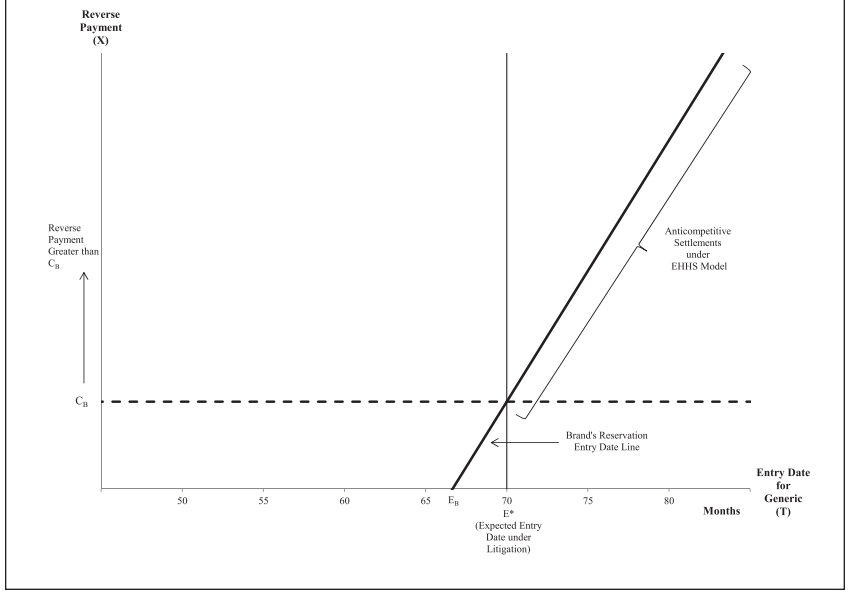
The essence of EHHS's argument is that under some circumstances reverse payments can delay competition to the detriment of consumers. EHHS present a model that purports to represent the decision calculus facing a Brand subject to a patent challenge by a Generic under Hatch-Waxman. This model considers the Brand's incentives by comparing the Brand's expected profits under a settlement to its expected profits from litigating.

Using the notation employed in the EHHS model, the Brand holds a patent with a remaining lifetime of T periods, and the Brand places a probability P on winning the patent litigation. If the Brand wins the litigation, its patent will remain valid and the Brand will earn a profit stream undiminished by Generic competition through the end of the patent period. If it loses the litigation, entry will occur and it will face diminished profits immediately (designated as time 0).[10] Litigation is costly for the Brand, and its cost of pursuing litigation to its conclusion is denoted as C_B.

Under the EHHS model, settlement involves two parameters: a negotiated entry date for the Generic (E) and, possibly, a payment (X) from the Brand to the Generic. EHHS consider a settlement to be anticompetitive if it leads to a longer period of patent protection and a correspondingly shorter period of Generic competition than would be expected to occur through litigation.[11] In their model, this situation occurs if and only if E > PT—that is, if the negotiated entry date under settlement is later than the probability the patent will be upheld multiplied by the remaining patent period, i.e., the "expected entry date."

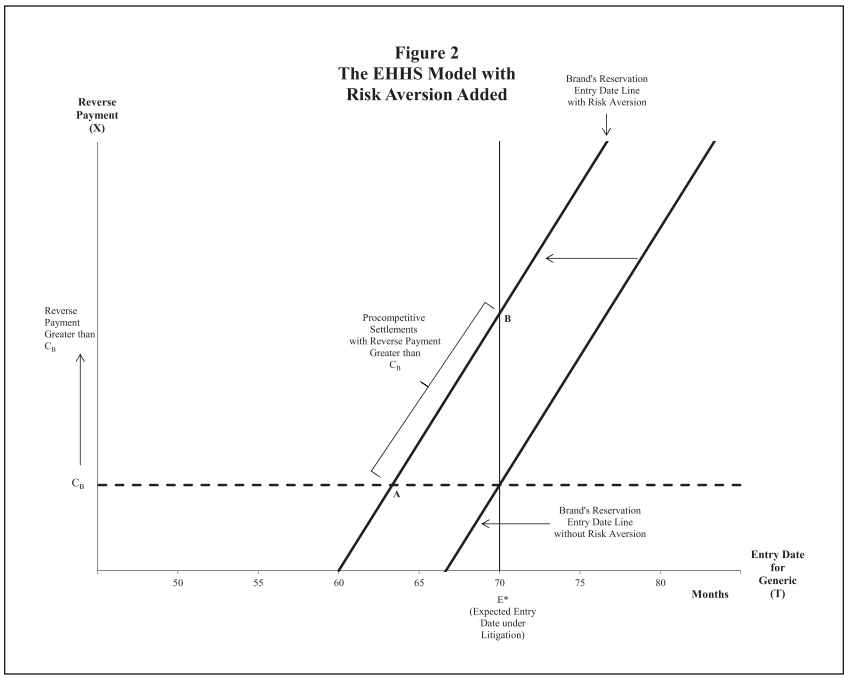
The probability that the patent would be upheld in litigation is not observable, so it is not possible to compare directly the settlement date and the expected date of entry under litigation. EHHS claim, however, that whether a settlement resulted in an anticompetitive delay can be inferred by considering the size of the reverse payment. According to EHHS, the entry date under settlement will be later than the expected entry date under litigation if and only if the reverse payment exceeds the Brand's avoided litigation costs. This

Figure 1
The EHHS Model



result occurs because, under the specific assumptions of the EHHS model, the Brand would agree to a settlement with a reverse payment in excess of its litigation costs only if the settlement delayed the Generic's entry beyond the date the Brand expected entry to occur under litigation.[12]

Figure 1 shows the earliest entry date the Brand would be willing to accept in a settlement under the EHHS model, which is called the Brand's reservation entry date.[13] With this entry date, the Brand would be indifferent between the settlement and litigation, given its litigation costs, its expectations of success in litigation, its attitude toward risk, and any payment it makes as part of the settlement. In Figure 1, it is assumed that 100 months remain in the patent period and that the Brand perceives it has a 70 percent chance of prevailing in litigation. With no reverse payments, the Brand's reservation entry date is E_B. E_B precedes the expected entry date under litigation (E*, or 70 months) because the Brand is willing to accept earlier entry to avoid litigation costs, depicted as C_B. With any payment it makes to the Generic under a settlement, a later reservation entry date is needed for the Brand to remain indifferent between litigation and settlement, so the Brand's reservation entry-date line slopes upward. As depicted in Figure 1, if reverse payments exceed the Brand's litigation costs under the EHHS model, the Brand will only agree to a settlement that allows Generic entry after the expected entry date under litigation.



The EHHS Result Does Not Always Hold When Other Factors Are Considered

EHHS focus on only one factor that can affect the Brand's reservation entry date—its out-of-pocket litigation costs. Indeed, the EHHS model recognizes that the incentive to avoid litigation costs can encourage settlements on the part of the Brand that are procompetitive, because these settlements allow entry before the expected entry date.[14] However, additional factors may result in settlements with entry dates earlier than expected under litigation even when reverse payments are greater than the Brand's avoided out-of-pocket litigation costs. The issue in a rule-of-reason analysis under *Actavis* is how to identify such settlements. The EHHS model cannot do so because it focuses only on litigation costs but disregards other factors, such as risk aversion.

EHHS assume that the Brand is risk-neutral.[15] The implications of this assumption can be significant and can drive the results of their model. All litigation is risky in that its outcome is inherently uncertain and potentially affected by legal error. Given a choice between receiving a payment with certainty and an uncertain outcome with an expected value equal to that payment, a risk-averse firm prefers the certain payoff.[16] Consequently, the Brand may be risk-averse because it places value on the ability to reduce the uncertainty associated with a litigated outcome, quite apart from any differences from other litigants in the expectation it may have regarding the strength of its patent.[17]

A Brand's settlement decision could be affected by risk aversion if, for example, a substantial portion of the Brand's profits come from the drug that is the subject of the patent litigation.[18] The Brand is likely to be particularly affected by risk if it stands to lose significant profits or rents on its investments. The more profitable the drug, the more risk the Brand bears from litigation.[19]

Risk aversion can have a significant effect on the settlement decision of the Brand because settlement generally eliminates the litigation risk. A risk-averse Brand may be willing to accept a settlement that allows for Generic entry on a date that precedes the entry date expected under litigation. For example, a Brand with an expectation that it has a 70 percent chance of prevailing in litigation may nonetheless agree to a settlement allowing entry by the Generic at 60 (out of 100) months if it is sufficiently risk-averse.

Once risk aversion is considered, EHHS's principal conclusion no longer holds: a reverse payment in excess of the Brand's out-of-pocket litigation costs does not imply the settlement is anticompetitive. This result is illustrated in Figure 2, which shows that risk aversion has the effect of shifting the Brand's reservation entry date earlier because risk aversion increases the benefit to the Brand of a settlement (with a certain entry date) compared to the uncertain prospect of litigation.[20] As a result, procompetitive settlements can occur even though reverse payments exceed the Brand's direct litigation costs. In Figure 2, settlements along segment AB would be acceptable to the Brand, would have reverse pay-

ments exceeding the Brand's direct litigation costs, and yet would be procompetitive in allowing Generic entry earlier than expected under litigation. The height of the point B in Figure 2 may be interpreted as the Brand's litigation costs inclusive of both direct out-of-pocket costs and the costs of bearing litigation risks.

EHHS acknowledge the potential impact of risk aversion on the analysis of reverse payments but appear to discount the relevance of risk aversion for at least two reasons.[21] First, they interpret the *Actavis* decision to imply "that payments to avoid even a small risk of competition are antitrust violations."[22] The Supreme Court, however, discusses risk aversion and reverse payments in a context where a large payment is intended "to maintain supracompetitive prices to be shared among the patentee and the challenger," and in which the payment "likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."[23]

The *Actavis* opinion in this context logically seeks to condemn reverse payments that delay Generic entry beyond the expected date on which entry would occur with litigation. EHHS's more expansive interpretation, however, goes beyond the *Actavis* decision. The *Actavis* decision indicates that settlements without explicit reverse payments are not unlawful, even though they eliminate the "risk of competition" for the period prior to the entry date under the settlement.[24] Indeed, any settlement that maintains the Brand's exclusivity for even a minimal period eliminates some "risk of competition," however small, during this period.[25] There is no economic basis for concluding, however, that such a settlement results in anticompetitive harm if, in the alternative, Generic entry would have been expected to occur later. As Figure 2 shows, a failure to allow settlements along segment AB of the Brand's reservation entry-date line would cause competitive harm because it would preclude settlements that permit entry at a date earlier than would be expected under litigation.

EHHS acknowledge that it is possible "that without a large reverse payment the defendants would have litigated their patent dispute and, with a highly risk-averse patentee, this litigation conceivably could have made consumers worse off in expectation."[26] EHHS claim, however, that the "overwhelming majority of all patent litigation settles; the main question is on what terms."[27] The apparent implication of EHHS's statement is that most or all patent settlements that involve reverse payments would have settled, albeit on different terms, were reverse payments not permitted.

EHHS's claim that most patent litigation settles is irrelevant, since most such litigation likely settles without a need for a reverse payment.[28] The *Actavis* Court, however, focused on the subset of patent litigation that settles with a reverse payment. The relevant issue for competition policy is not whether reverse payments are necessary for most settlements. Rather, the relevant questions are whether it is appropriate to presume anticompetitive harm when a reverse payment occurs and whether it is reasonable to presume that most cases that settle with reverse payments would also settle were such payments not permitted. We believe the answer to both questions is no.

The significance of a Brand's risk aversion in this context is not that it provides a justification for anticompetitive settlements that delay entry beyond the date expected from litigation. Rather, risk aversion is significant because it can induce a Brand to accept a settlement with accelerated entry relative to the expected entry date under litigation, with associated benefits for the Generic as well as for consumers. Thus, a settlement involving a risk-averse Brand may include a large reverse payment but still permit entry before the date that would be expected through litigation.[29]

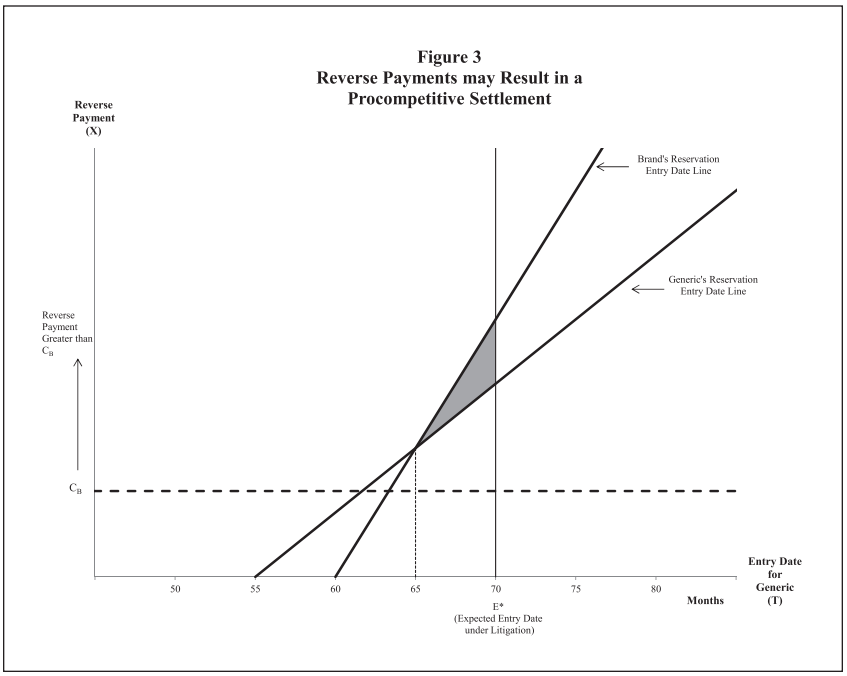
Reverse Payments May Permit Settlements that Enhance Consumer Welfare

The EHHS model considers settlement only from the perspective of the Brand. In reality, a voluntary settlement can only occur through mutual agreement between the Brand and the Generic. The effect of a reverse payment must therefore be considered in light of the likelihood of a settlement without a reverse payment.

Under certain conditions, mutually beneficial settlements may occur between the Brand and the Generic that do not involve reverse payments. When these conditions do not hold, reverse payments may be required to reach a settlement that enhances consumer welfare and therefore should be judged lawful under the Supreme Court's rule-of-reason standard.

The clearest examples occur when (a) absent a reverse payment the latest entry date on which the Generic is willing to settle is earlier than the earliest entry date on which the Brand is willing to settle, and (b) the earliest entry date on which the Brand is willing to settle occurs before the expected entry date under litigation. A reverse payment may enable the Generic's reservation entry date to "catch up" with the Brand's reservation entry date, thereby permitting a settlement.[30] Thus, while a reverse payment will result in a later reservation entry date for the Brand, it may do so from an earlier starting point and, thus, may result in a procompetitive settlement with an entry date that is earlier than the expected date under litigation.

Litigation can be more difficult to settle when the Brand and the Generic differ in their expectations of the likelihoods of different trial outcomes. By way of example, assume, as before, that 100 months remain on the Brand's patent, that the Brand perceives it has a 70 percent likelihood of succeeding in litigation, and that the Brand's perception reasonably reflects the likelihood that the patent would be found valid in litigation. In contrast, assume that the Generic believes it has a 50 percent likelihood of prevailing at litigation. Given these differing expectations, assume that after accounting for avoided litigation costs and risk aversion, the earliest the Brand is willing to accept entry with a settlement is 60 months, and the latest date on which the Generic is will-



ing to enter under a settlement is 55 months. Under such a scenario, no settlement is possible without a reverse payment because there is no possible settlement entry date that both the Brand and the Generic would prefer to litigation.

Including a reverse payment can create mutually beneficial settlement solutions for the Brand and the Generic that include settlements in which entry occurs prior to the expected entry date under litigation. Figure 3, which reproduces Figure 2 and also includes the Generic's reservation entry-date line, provides an illustration. The Generic's reservation entry-date line represents the latest entry date the Generic would accept in a settlement, along with a particular level of reverse payments, given the Generic's litigation costs and its perceived likelihood of success in litigation.

With no reverse payment, the Generic's reservation entry date under settlement is 55 months, while the Brand's reservation entry date is 60 months. No settlement is possible without payment by the Brand to the Generic, but as the payment grows the Generic's reservation entry date eventually reaches, and then surpasses, the reservation entry date for the Brand. As depicted in Figure 3, the earliest date on which agreement is possible is at 65 months, which is earlier than the expected entry date under litigation (70 months). Thus, in this example, settlement would not be possible without a reverse payment. The reverse payment bridges the gap between the parties and allows them to reach a mutually agreeable solution that permits Generic entry on a date that precedes the expected entry date under litigation.

Another circumstance that gives rise to procompetitive settlements involving reverse payments is the previously discussed expectation of entry by a third firm with a non-infringing product.[31] Others include situations in which the Brand and the Generic have different views or different access to information about the duration of the market for the patented product or have different time values of money.[32]

The example addressed in Figure 3 illustrates several important points about the potential effect of reverse payments. First, there can be no presumption from the mere existence of a reverse payment that Generic entry has been delayed. As indicated in the *Actavis* opinion, analysis of the effect of reverse payments must be made in comparison with the likely outcome in the absence of reverse payments.[33] In Figure 3, absent a reverse payment, settlement would not occur because the Generic's reservation entry date precedes the Brand's reservation entry date. Instead, the parties would have proceeded to litigation, with entry expected later than what would have occurred under settlement.

Second, there is no economic basis to presume that a reverse payment in excess of avoided direct litigation costs implies that consumers are worse off under settlement than they would have been with litigation. In Figure 3, the earliest possible settlement would result in entry in month 65, and such a settlement benefits consumers even though the level of reverse payments exceeds the Brand's out-of-pocket litigation costs. Indeed, additional possible settlements, each allowing entry by the Generic between months 65 and 70, would have been beneficial to consumers relative to litigation, but would have necessarily involved reverse payments in excess of the Brand's direct litigation costs.[34] The shaded region in Figure 3 depicts the range of potential procompetitive settlements—combinations of negotiated entry dates and reverse payments—between the Brand and the Generic.

Finally, there is no economic basis to presume that if a settlement includes a reverse payment, a different settlement more favorable to consumers would have been available without a reverse payment. In Figure 3, a settlement allowing entry in month 65 represents the earliest possible entry date available under a mutually beneficial settlement between the Brand and the Generic.

Conclusion

EHHS's conclusion that anticompetitive effects can be inferred from reverse payments in excess of the Brand's direct litigation costs holds only under specific circumstances. As such, the EHHS model is a special case and does not support a generally applicable result. Also, the standard proposed by EHHS would condemn some procompetitive settlements.

EHHS have sought to devise a relatively simple and straightforward test to analyze an extremely complex issue. In doing so, they have ignored the Supreme Court's guidance in *Actavis*, which rejected applying presumptive rules in matters involving a reverse payment, and which, instead, called for

consideration of a variety of "complexities" in such cases.[35] In addition to avoided out-of-pocket litigation costs, relevant factors in patent settlements involving a reverse payment may include *inter alia* the risk tolerance of the parties, the level of the drug's sales, the parties' expectations and information asymmetries related to future competition for the drug, the parties' subjective views of the likely outcome of the litigation, the parties' differences in the time-value of money, the applicability of Hatch-Waxman first-filer exclusivity, the relative size of the alleged net reverse payment, and of course the extent of the alleged delay and associated diminution of competition. While more complex than the rule proposed by EHHS, an analysis that accounts for a multitude of case-specific factors is typical of the inquiry that normally accompanies rule-of-reason antitrust cases. ■

1 FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013). Throughout this article, we adopt the Supreme Court's terminology and refer to monetary consideration paid in a patent settlement by a Brand to a Generic as a "reverse payment."

2 *Id.* at 2237.

3 Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, ANTITRUST, Fall 2013, at 18.

4 *Id.* at 17.

5 *Id.* at 17–18. We note that EHHS take the position that any consideration (other than the value of a negotiated early entry date) flowing from the Brand to the Generic should qualify as a payment. The *Actavis* Court makes no such statement and a recent district court decision, citing the *Actavis* opinion, declined to take this position. *See In re* Lamictal Direct Purchaser Antitrust Litig., No. 2:12-cv-00995-WHW-CLW (D.N.J. Jan. 24, 2014).

6 *Id.* at 18.

7 *Actavis*, 133 S. Ct. at 2237 (emphasis added). Indeed, if EHHS's view were correct, the Supreme Court could simply have stated that any reverse payment in excess of direct litigation costs is presumptively unlawful.

8 For the purposes of this article we define settlements to be procompetitive if they result in Generic entry occurring earlier than would have been expected under litigation.

9 *See, e.g.*, John Nash, *Two-Person Cooperative Games*, 21 ECONOMETRICA 128 (1953).

10 This formulation assumes that a determination of validity and/or infringement is instantaneous and that Generic entry could occur immediately upon such a determination. In reality, absent a settlement, particularly when appeals are considered, it could be several years before there is a final judicial determination.

11 Edlin et al., *supra* note 3, app. EHHS ignore some potential social benefits from settlements, including the preservation of judicial resources and elimination of risk to the firms and consumers associated with the uncertain timing of Generic entry under litigation. *See, e.g.*, Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 658 (2004). EHHS also do not consider any potential long-run effects of opportunities to settle patent disputes on the incentives of firms to innovate.

12 Of course, a Brand may also compensate a Generic for the Generic's provision of valuable services, and the EHHS model accounts for this possibility. For present purposes, we ignore this consideration.

13 This depiction of a Brand's decision calculus in deciding between settlement and litigation is adapted from the Appendix of Willig and Bigelow, as are Figures 2 and 3. *See* Willig & Bigelow, *supra* note 11, app.

14 Put differently, EHHS's proposed standard would provide a safe harbor for reverse payments up to the amount of the avoided litigation costs for the Brand, even if no other goods or services were provided by the Generic to the Brand. *See* Edlin et al., *supra* note 3, at 18.

15 *Id.* at n.7.

16 The cost of risk bearing to a risk-averse firm is represented by a risk premium, the amount the firm would be willing to pay to avoid bearing an actuarially fair risk, for a given variance. The costs of bearing litigation risk are an increasing function of the size of the profit flow to the Brand, of the Brand's degree of risk aversion, and of the degree of uncertainty about the litigation outcome. *See* Willig & Bigelow, *supra* note 11, at 682–83. Conceptually, the risk premium may be added to the out-of-pocket or direct costs of litigation.

17 *See* John W. Pratt, *Risk Aversion in the Small and in the Large*, 32 ECONOMETRICA 122, 122–36 (1964). Conversely, a risk seeker prefers a gamble to a certain payoff with the same expected value. *See* JACK HIRSHLEIFER, INVESTMENT, INTEREST AND CAPITAL 224–25 (1970).

18 The Brand may be risk-averse, not only over different potential income streams, but also over real variables, such as the date on which Generic entry occurs, if it intends to make production, marketing, or R&D investments that depend on the expected timing of Generic entry for the molecule in question. The settlement provides the firm with information about future outcomes, which is valuable even to a risk-neutral firm that must plan for the future. Given the high level of uncertainty over timing associated with the process and outcome of patent litigation, the Brand may be willing to pay a substantial premium to resolve that uncertainty prior to making its marketing and specific investment decisions. Uncertainty over cash flows that are important for financial support of R&D could reduce pharmaceutical innovation that is important both commercially and socially. *See* 13 HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATIONS 44 (1999) (noting that "firms typically respond to uncertainty by being less aggressive" in their investment decisions).

19 While owners of many firms may be capable of diversifying risks, managers within firms may have a substantial share of their current (and prospective future) wealth concentrated in their employer. Such managers may be incapable of eliminating such risk through diversification, given the nature of their human capital. *See* Frank H. Easterbrook, *Two-Agency Cost Explanations of Dividends*, 74 AM. ECON. REV. 650, 653–54 (1984); RICHARD E. CAVES, MULTINATIONAL ENTERPRISE AND ECONOMIC ANALYSIS 26 (1982). Information asymmetries inevitably surrounding R&D tend to create capital market imperfections that make internal funding of R&D from cash flows significantly more efficient, while such funding can be significantly vulnerable to patent-litigation risks.

20 This result is demonstrated formally in the Technical Appendix to this article, *available at* http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/harris_appx_12_03f.pdf.

21 Edlin et al., *supra* note 3, at 20.

22 *Id.*

23 *Actavis*, 133 S. Ct. at 2236.

24 *Id.* at 2233.

25 There is always some risk (e.g., due to legal error) that a patent, however strong, will be found invalid or non-infringed. A settlement may therefore provide for Generic entry well before the expected entry date under litigation, yet still eliminate the small chance that the Generic would enter immediately because the Brand loses the patent litigation.

26 Edlin et al., *supra* note 3, at n.51.

27 *Id.*

28 In a more traditional setting, an alleged infringer has already entered and may be liable for significant damages if it is found to have infringed a patent. When a settlement occurs, the alleged infringing firm will typically pay only a portion of its potential damages to the patent holder. Such a settlement may therefore be viewed as conveying value to the alleged infringing firm because the patent holder relinquishes its claim on some portion of the potential damages. *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1046–49 (2004). The Supreme Court in *Actavis* specifically noted that such "traditional" settlements are lawful. *See Actavis*, 133 S. Ct. at 2233. In contrast,

there are typically no damages to the Brand in the Hatch-Waxman context because the Generic can challenge the patent without entering the market.

[29] Other factors can lead a Brand to prefer settlement with entry preceding the expected entry date under litigation. One such factor is the possibility of predictable entry by a third firm, such as when a firm plans to enter with a chemically different product that competes closely with the Brand's product, not an uncommon occurrence in the pharmaceutical industry. *See* Willig & Bigelow, *supra* note 11, at 673–75, for a detailed discussion of the effect of such expected entry.

[30] This convergence occurs because for any given increment in reverse payment, the Generic's reservation entry date is delayed more than the Brand's.

[31] As Willig and Bigelow discuss, the expectation of entry by a firm other than the Brand and the Generic has an asymmetric effect on the reservation entry dates for the Brand and the Generic and thus can preclude settlement absent a reverse payment. *See* Willig & Bigelow, *supra* note 11, at 673–75.

[32] Willig and Bigelow discuss the implications of asymmetric information. *See* Willig & Bigelow, *supra* note 11, at 667–72. Schildkraut addresses differences in the time value of money in an example he terms "Cash-Strapped Generic." *See* Schildkraut, *supra* note 28, at 1058–59. Under such a situation, the Generic's managers may act as if they are risk-preferring (*see* Susan Rose Ackerman, *Risk Taking and Ruin: Bankruptcy and Investment Choice*, 20 J. LEGAL STUD. 277 (1991)), in which case they would prefer to litigate rather than accept settlement with entry on a date equal to the expected entry date under litigation. The Generic may be risk-seeking with respect to a specific Hatch-Waxman patent challenge if it views that challenge as part of a portfolio of challenges. Since a Hatch-Waxman challenge does not involve an actual patent violation, it contains little or no actual risk for the Generic apart from the costs it must incur to file a Paragraph IV Certification. Consequently, a Generic may be aggressive with respect to an individual Hatch-Waxman challenge because this added risk can, in effect, be reduced through portfolio diversification.

[33] *Actavis*, 133 S. Ct. at 2224–25.

[34] Of course, settlement also provides consumers with assurance of Generic entry before patent expiration, where no such entry would have occurred in the event the patent is upheld. Risk-averse consumers would value the risk reduction that comes from such a settlement. *See* Willig & Bigelow, *supra* note 11, at 658.

[35] *Actavis*, 133 S. Ct. at 2237.